

IN THE TITLE:

~~A PROTEIN INVOLVED IN CARCINOMA~~ Detection of MAL2 protein in carcinoma
diagnosis

IN THE SPECIFICATION:

In the paragraph bridging pages 2-3 of the application as filed, paragraph [0006] of the published application:

[0006] Breast cancer is the most frequently diagnosed cancer in women. The implementation of screening programs for the early detection of breast cancer, and the advent of anticancer treatments, such as chemotherapy, radiotherapy and anti-oestrogen therapies, to augment surgical resection have improved the survival of breast cancer patients. However, some breast tumours become refractory to such treatments, as the cancer cells develop resistance to chemotherapy drugs or lose their hormone sensitivity, leading to recurrent or metastatic disease which is often incurable. More recently, attention has focussed on the development of immunological therapies (Green, MC. *et al.*, 2000, *Cancer Treat. Rev.* 26:269-286; Davis, ID., 2000, *Immunol. Cell Biol.* 78:179-195; Knuth, A. *et al.*, 2000, *Cancer Chemother Pharmacol.* 46:S46-51; Shiku, H. *et al.*, 2000, *Cancer Chemother. Pharmacol.* 46:S77-82; Saffian, DC. *et al.*, 1999, *Cancer Metastasis Rev.* 18:437-449), such as cancer vaccines and monoclonal antibodies (mAbs), as a means of initiating and targeting a host immune response against tumour cells. Herceptin-HERCEPTIN®, a mAb that recognises the erbB2/HER2-neu receptor protein, is used as a treatment for metastatic breast cancer. In combination with chemotherapy, Herceptin-HERCEPTIN® has been shown to prolong the time to disease progression, when compared to patients receiving chemotherapy alone (Baselga, J. *et al.*, 1998, *Cancer Res.* 58:2825-2831). Herceptin-HERCEPTIN®, however, is only effective in treating the 10-20% of patients whose tumours over-express the erbB2 protein. Thus, an increasingly important need exists to identify new breast cancer associated proteins for use as sensitive and specific biomarkers for the diagnosis of breast cancer in living subjects. Additionally, there is a clear need for new therapeutic agents for the treatment of breast cancer that work quickly, potently, specifically, and with fewer side effects.